

Remarks:

Claims 1-2, 4-8, and 12-17 remain for consideration in this application with claims 1 and 12 being in independent format. Claims 1 and 4-8 were noted as being allowable in the most recent office action.

Claim 2 was withdrawn from consideration as being directed to a non-elected invention. Applicants have amended claim 2 such that it now is directed to a non-elected invention by deleting the word "nucleotides" and substituting "amino acids" therein. Such an amendment is clearly supported in the specification as the specification is directed toward amino acids and not the nucleotide sequences encoding those amino acids. Accordingly, applicants respectfully request that this amended claim be considered. Moreover, applicants note that claim 2 depends from claim 1, which has been noted as allowable, and should also be allowable.

Claims 12 and 14-17 were rejected under 35 U.S.C. 112, first paragraph. Specifically, it was alleged that there was insufficient support for the limitations that the claimed peptide has between 15 and 39 amino acids, and that it has at least 15 contiguous amino acids from SEQ ID NO. 1. The issue of support for these phrases in these claims was presented in the previous office action response and is duplicated below, with minor changes to account for the amendment.

Independent claim 12 now recites:

A method of attracting a leukocyte to a wound location or area of inflammation within an organism through chemotaxis, said organism having an immune system including leukocytes therein, said method comprising the steps of:
administering a peptide to the organism, said peptide having from 15 to 39 amino acids and having therein at least 15 contiguous amino acids from SEQ ID NO: 1; and
causing said leukocyte to migrate to said location or area.

Support for this claim is found in the present specification as well as in the specification of the “parent” application, which is now US Patent No. 5,830,993. This parent application was specifically incorporated by reference in the present application at page 1, lines 6-8. Specifically, the present application provides support for the phrases “A method of attracting a leukocyte to a wound location or area of inflammation within an organism through chemotaxis” and “causing said leukocyte to migrate to said location or area” at page 3, line 26 to page 4, line 2, which recites:

The present invention is predicated upon the discovery that specific peptides (e.g., PR-39) are capable of 1) inhibiting O₂⁻ synthesis by leukocyte enzymes (e.g., NADPH oxidase), and 2) attracting leukocytes (e.g., neutrophils). These peptides can be used as novel medicaments that fight infection by attracting leukocytes to a wound site, yet restrict tissue damage at the wound site caused by excessive oxygen radicals produced by these leukocytes. Preferably, these peptides have a sequence included in PR-39 (e.g., Sequence ID Nos. 1 and 2 for peptides capable of inhibiting O₂⁻ production, and Sequences ID Nos. 1, 2, 5, 6, and 7 for peptides capable of attracting leukocytes).

Additionally, page 14, lines 5-12 and Fig. 9, provide further support. For example, page 14 recites:

Influence of PR-39 on neutrophil chemotaxis. Phagocytic cells migrate from the blood to areas of inflammation in response to chemotactic agents. Fig. 9 shows that PR-14, PR-15, PR-16, PR-26, and PR-39 are chemotactic agents for neutrophils (PR-14, PR-15, PR-16, and PR-26 are used at 1 μM, and PR-39 was used at 0.05 μM; the chemoattractant C5a, a positive control, was used at 1 x 10⁻⁸M; starred entries are different from the control, P < 0.05). Fig. 10 shows a dose response of PR-39 for neutrophil chemotaxis. The ability of PR-39 to function as a chemotactic agent increases the probability that sufficient phagocytic cells are present at an inflammatory site to limit an infection.

US Patent No. 5,830,993, which was incorporated by reference by the present application and is related to the present application in that the present application is a divisional application of a continuation-in-part application to the application from which US Patent No. 5,830,993 issued, provides support for the limitation of "said peptide having from 15 to 39 amino acids and having therein at least 15 contiguous amino acids from SEQ ID NO: 1." Column 2, lines 4-8, recites:

In preferred forms, the invention relates to isolated anti-microbial peptides comprising a peptide compound having a partial amino acid sequence of PR-39 (SEQ ID NO: 1) with at least 15 and less than all of the amino acid residues of PR-39, beginning at the -NH₂ terminal thereof.

This patent also disclosed the sequences of SEQ ID NOS: 1, 2, 5, 6, and 7, all of which are partial amino acid sequences of PR-39 as shown by Fig. 1 of that patent and Fig. 1 of the present application. Moreover, the present specification provides five examples of peptides (SEQ ID NOS: 1, 2, 5, 6, and 7, which are identical to the same sequences listed above as having been disclosed in the incorporated patent) that have from 15 to 39 amino acids, at least 15 contiguous amino acids from SEQ ID NO: 1, administering these peptides to an organism, and causing a leukocyte to migrate to a wound location or area of inflammation through chemotaxis.

Such disclosure satisfies the requirements of 35 U.S.C. 112, first paragraph and applicants respectfully request that this rejection be withdrawn.

Claims 12-17 were rejected under 35 U.S.C. 112, first paragraph for a lack of enablement for the phrase "attracting a leukocyte to a wound location or area of inflammation" as well as "organism." With respect to the "attracting" phrase, it is well documented that leukocytes are inherently attracted to wound locations and areas of inflammation. This fact is noted in the present

specification at page 14, lines 5-12 (recited above) and Figs. 9 and 10, which further support applicants' assertions. It was further determined that the administration of peptides in accordance with the invention increases the migration of neutrophils to wound sites or areas of inflammation through chemotaxis, a fact also noted in this same passage. It was also found that peptides in accordance with the present invention bind to the p47^{phox} cytosolic component of the NADPH oxidase complex. Working examples are not required by 35 U.S.C. 112 and the present application includes the assertion that the "peptides can be used as novel medicaments that fight infection by attracting leukocytes to a wound site, yet restrict tissue damage at the wound site caused by excessive oxygen radicals produced by these leukocytes." (Page 3, lines 28-30). Those of skill in the art would be able to identify appropriate methods and locations of administration without undue experimentation, thereby satisfying MPEP 2164.01(c).

With respect to the term "organism," applicants have amended the claim to recite that the organism must have an immune system having leukocytes. As the invention is predicated on chemotaxis, the organism within which the invention will be effective is only limited to those that have an immune system having leukocytes therein.

Accordingly, applicants assert that all 112 issues have been overcome and that a Notice of Allowance is in order and is, therefore, courteously solicited.

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Any additional fee which is due in connection with this amendment should be applied against
our Deposit Account No. 19-0522.

Respectfully submitted,

By



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